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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,683	09/02/2005	Frederic Impellizzeri	1811-64	7190
24106	7590	05/18/2007		
EGBERT LAW OFFICES 412 MAIN STREET, 7TH FLOOR HOUSTON, TX 77002			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/530,683

Applicant(s)

IMPELLIZZERI, FREDERIC

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/14/2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-20, 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Hawkes (U.S. Patent No. 6,679,883).

Hawkes discloses a locking osteosynthesis device comprising a plate having a plurality of openings formed therein, each of the plurality of openings having a diameter, the plate being formed of a metallic material; a plurality of inserts respectively fixedly

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and non-rotationally received in the plurality of openings (see Abstract, line 6-9, col. 7, lines 65-end and col. 8, lines 1-52), each of the plurality of inserts defining a hole having a smooth wall and a diameter less than the diameter of the opening, each of the plurality of inserts being formed of a biocompatible polymeric material (col. 11, lines 29-32, e.g. UHMWPE); and a plurality of bone screws respectively received in the hole of the plurality of inserts, each of the plurality of bone screws having a thread (ref. #90) on an outer surface thereof, the biocompatible polymeric material suitable for allowing, i.e. capable of allowing, a self-tapping of the smooth wall of the hole with the thread of the plurality of bone screws, the plurality of bone screws having a head (ref. #96) locked in the plurality of inserts when the thread of the bone screw engages an underlying surface, i.e. the bone is the underlying surface. The plurality of inserts being formed of a thermoplastic polymer (UHMWPE). The hole has a conical shape. The plate is formed of titanium. The plurality of inserts being molded respectively into the plurality of openings. The plurality of inserts being mechanically secured respectively in the plurality of openings (see col. 8, lines 16-25). The plate has a shoulder extending into each of the plurality of openings (retaining lip, ref. #78).

It is noted that Hawkes specifically notes that ridges or projections are desirable on the screw head in order to achieve a mechanical lock (col. 8, lines 7-23).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkes (U.S. Patent No. 6,679,883).

Hawkes discloses the claimed invention except for the plurality of inserts being formed of a polyether ether ketone material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the plurality of inserts of a polyether ether ketone material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkes (U.S. Patent No. 6,679,883) in view of Weil et al. (U.S. Patent Publication Application (2003/0028193)).

Hawkes disclose the claimed invention except for self-tapping screws having a head having a conical threading formed thereon. [Hawkes only discloses that ridges or projections are desirable on the conical screw head in order to achieve a mechanical lock (col. 8, lines 7-23) Also, Hawkes discloses in col. 6, lines 28-34, that the fastener may be any suitable fastener for attaching the plate to the vertebrae]].

Weil et al. disclose a self-tapping screw having a head having a conical threading formed thereon that eliminates the step of drilling a hole prior to screwing in of the screw while providing a mechanical interlock.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provide the plate of Hawkes with the fastener, i.e. the self-tapping screw having a head having a conical threading formed thereon, in view of Weil et al. to eliminate the step of drilling a hole prior to screwing in of the screw while providing a mechanical interlock.

### ***Response to Arguments***

Applicant's arguments filed 02/14/2007 have been fully considered but they are not persuasive.

Applicant amendments are not deemed sufficient to overcome the prior art of record. Applicant argues that the Hawkes reference does not disclose "fixedly and rotationally received" since the reference states "that the receiving member is configured....to remain movable....in a semiconstrained manner." The examiner respectfully disagrees, since the "semiconstrained" plate is only one embodiment discussed in the reference. The reference also discusses an alternative "constrained" embodiment (see col. 6, lines 50-55, col. 7, lines 65-end, col. 8, lines 53-55). In the constrained embodiment, the receiving member, or insert, is locked in place, i.e. it is fixedly and rotationally received as required by Applicant's current claim recitations.

Also, it is noted that the phrase "suitable for allowing..." is being considered a functional limitation. With regard to functional statements in the claims, they do not impose any structural limitations on the claims distinguishable over Hawkes, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ

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235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The Hawkes reference discloses threads (ref. #90) that would be capable of tapping the polymeric material if one chose to apply a sufficient force to the polymeric material using the threaded shaft portion of the screw of Hawkes. The head of the bone screw will be locked (in the constrained embodiment) when the threads (ref. #90) engage an underlying surface, i.e. the bone surface.

It is noted that Applicant's arguments that the Hawkes reference does not relate to a different field of orthopedic surgery are not persuasive. Clearly, both the Hawkes reference and the instant application relate to the fixation of bone and can be considered to be in the same field of endeavor. Moreover, the applied rejection is a 102(e) anticipation rejection; accordingly, the prior art anticipating the claimed invention may come from any field of endeavor so long as all the claimed features appear in the prior art.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., very small dimensions and a thickness less than 1mm) are not recited in the

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rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's arguments with respect to the claims rejected under Hawkes (U.S. Patent No. 6,679,883) in view of Bono (U.S. Patent No. 5,954,722) have been considered but are moot in view of the new ground(s) of rejection.

The rejections are deemed proper.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

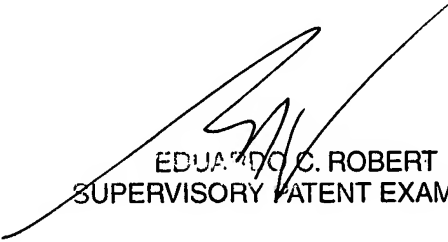
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER